UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

BURTON L. APPLETON,	:		
	:		
Plaintiff,	:	Civil Action No.:	02-1043 (RMU)
	:		
v.	:	Document Nos.:	32, 36, 40
	:		
FOOD AND DRUG ADMINISTRATION and DEPARTMENT OF HEALTH AND HUMAN SERVICES,	:		
	:		
Defendants.	:		

MEMORANDUM ORDER

GRANTING THE APPLICANTS' MOTIONS TO INTERVENE;
DIRECTING THE PLAINTIFF AND THE DEFENDANTS TO SUBMIT A PRODUCTION SCHEDULE

Pro se plaintiff Burton Appleton, a former Food and Drug Administration ("FDA") chemist, brings this action to compel FDA and the Department of Health and Human Services ("HHS") (collectively, "the defendants") to reply fully to his Freedom of Information Act ("FOIA") request for records regarding the drug levothyroxine sodium ("LS"). In response, the defendants notified various LS manufacturers of the plaintiff's suit,[1] filed a partial answer, and moved the court for an *Open America* stay of proceedings.[2] Five LS manufacturers then moved to intervene.[3] The court granted the defendants' motion for a stay, but held the production schedule in abeyance until the parties clarified the scope of the plaintiff's request. *Appleton v. Food & Drug Admin.*, 254 F. Supp. 2d 6 (D.D.C. 2003). At the same time, the court denied

[1] FDA provided notification to the LS manufacturers pursuant to 21 C.F.R. § 20.53, which FDA subsequently redesignated as 21 C.F.R. § 20.55. 68 Fed. Reg. 25,286 (May 12, 2003).

[2] *See Open Am. v. Watergate Special Prosecution Force*, 547 F.2d 605 (D.C. Cir. 1976).

[3] The five manufacturers were Jerome Stevens Pharmaceuticals, Inc.; Jones Pharma, Inc.; Abbott Laboratories; Lloyd Inc.; and Vintage Pharmaceuticals, Inc.

without prejudice the motions to intervene, stating that the LS manufacturers could refile their motions after the scope of the plaintiff's request becomes clear. *Id.*

Pursuant to the court's order, the parties reported that they had clarified the scope of the plaintiff's request but were at an impasse over the proposed production schedule. Joint Status Report at 2, 9. Subsequently, however, the plaintiff asked the court to temporarily stay the case due to medical difficulties. Pl.'s Mot. for Stay at 1. The court granted a stay through February 9, 2004, and directed the plaintiff to indicate whether he wished to continue with the litigation. Order dated Jan. 5, 2004. The plaintiff informed the court that his condition had stabilized and that he was "sufficiently alive . . . so that he is able to prosecute his case in approximately normal fashion." Pl.'s Resp. at 1. In the interim, LS manufacturers Jerome Stevens Pharmaceuticals, Inc. ("Jerome Stevens"), Jones Pharma, Inc. ("Jones Pharma"), and Abbott Laboratories ("Abbott") (collectively, "the applicants") renewed their motions to intervene. Given the expiration of the temporary stay and the plaintiff's stated intent to continue with this action, the court now turns to the applicants' motions to intervene and the question of an appropriate production schedule.

Federal Rule of Civil Procedure 24 sets forth the requirements for intervention as of right and permissive intervention. FED. R. CIV. P. 24; *Fund for Animals, Inc. v. Norton*, 322 F.3d 728, 731 (D.C. Cir. 2003). First, Rule 24(a) provides for intervention as of right, stating that

> [u]pon timely application anyone shall be permitted to intervene in an action . . . when a statute of the United States confers an unconditional right to intervene; or . . . when the applicant claims an interest relating to the property or transaction which is the subject of the action and the applicant is so situated that the disposition of the action may as a practical matter impair or impede the applicant's ability to protect that interest, unless the applicant's interest is adequately represented by existing parties.

Id. As paraphrased by the D.C. Circuit, the rule indicates that an applicant's right to intervene depends on "(1) the timeliness of the motion; (2) whether the applicant claims an interest relating

to the property or transaction which is the subject of the action; (3) whether the applicant is so situated that the disposition of the action may as a practical matter impair or impede the applicant's ability to protect that interest; and (4) whether the applicant's interest is adequately represented by existing parties." *Fund for Animals*, 322 F.3d at 731; *see also Jones v. Prince George's County, Md.*, 348 F.3d 1014, 1017 (D.C. Cir. 2003) (listing the four elements of Rule 24(a) as "timeliness, interest, impairment of interest, and adequacy of representation"). In addition, an applicant must demonstrate that it has standing. *Jones*, 348 F.3d at 1017-18; *Fund for Animals*, 322 F.3d at 731-32.

Alternatively, Rule 24(b) authorizes permissive intervention for an applicant who timely files a motion when a federal statute confers a conditional right to intervene or the applicant's claim or defense has a question of law or fact in common with the main action. FED. R. CIV. P. 24(b). In considering a motion for permissive intervention, a court must determine whether the proposed intervention "will unduly delay or prejudice the adjudication of the rights of the original parties."[4] *Id.*

In this case, the applicants move to intervene as of right under Rule 24(a).[5] Jerome Stevens Mot. to Intervene ("Jerome Stevens Mot.") at 2; Abbott Mot. to Intervene ("Abbott Mot.") at 1; Jones Pharma Mot. to Intervene ("Jones Pharma Mot.") at 1-2. The court concludes that each applicant may intervene as of right. First, all three applicants moved to intervene in a timely fashion, filing their initial motions within two months of FDA's notification of the pending suit and their renewed motions within two months of the report of the plaintiff's

[4] In this circuit, "there is uncertainty over whether standing is necessary for permissive intervention." *In re Vitamins Antitrust Class Actions*, 215 F.3d 26, 31 (D.C. Cir. 2000). Given its conclusion today, the court need not address this question.

[5] In the alternative, Jones Pharma and Abbott move for permissive intervention. Jones Pharma Mot. to Intervene at 5-6; Abbott Mot. to Intervene at 7.

clarified request or the plaintiff's notice of his intent to continue with the litigation. *Fund for Animals*, 322 F.3d at 731; *Associated Builders & Contractors, Inc. v. Herman*, 166 F.3d 1248, 1257 (D.C. Cir. 1999) (noting that the court determines timeliness from the circumstances of the case pursuant to its sound discretion).

Second, the applicants have an interest in the subject of the action. *Fund for Animals*, 322 F.3d at 731. Each of the applicants submitted to FDA a new drug application ("NDA") that allegedly contains trade secrets and confidential information regarding its LS product.[6] Jerome Stevens Mot. at 11-12; Abbott Mot. at 5; Jones Pharma Mot. at 3-4. Given that the plaintiff's clarified request seeks all FDA reviews of approved LS NDAs, the applicants have an interest in the FDA information. Joint Status Report at 5-6. Third, disclosures resulting from the disposition of this action could impair the applicants' ability to protect their trade secrets or confidential information. *Fund for Animals*, 322 F.3d at 731; Jerome Stevens Mot. at 12-13; Abbott Mot. at 5-6; Jones Pharma Mot. at 4.

Fourth, the applicants have met their "minimal" burden of showing that the existing parties do not adequately represent their interests. *Fund for Animals*, 322 F.3d at 731, 735 (quoting *Trbovich v. United Mine Workers*, 404 U.S. 528, 538 n.10 (1972)). In contrast to the applicants' interest in protecting their trade secrets and confidential information, the plaintiff's interest lies in disclosure and FDA's interest lies in responding appropriately to the plaintiff's request. *Compare* Joint Status Report at 5-6 (listing the information the plaintiff seeks) *and* 21 C.F.R. § 20.55 (requiring that persons whose FDA records include trade secrets or confidential information intervene to defend the exempt status of the records or else risk FDA's public

[6] The court makes no statement as to whether the information contained in the applicants' NDAs in fact qualifies as trade secrets or confidential information.

disclosure of the records) *with* Jerome Stevens Mot. at 13 (stressing an interest in avoiding economic injury), Abbott Mot. at 6 (same), *and* Jones Pharma Mot. at 4-5 (same). As for standing, the applicants have shown that FDA's disclosure of their trade secrets or confidential information would cause them to suffer an injury-in-fact that intervention to defend against disclosure could redress. *Fund for Animals*, 322 F.3d at 732-33.

Accordingly, it is this 24th day of March, 2004, hereby

ORDERED that the applicants' motions [#32, #36, #40] to intervene are **GRANTED**;[7] and it is

FURTHER ORDERED that the Clerk of the Court shall file the applicants' answers [#23 Ex., #32 Ex. B, #36 Ex. A] on the date of this Memorandum Order; and it is

ORDERED that by no later than April 6, 2004, the plaintiff and FDA file a motion jointly proposing a schedule for the realistic, timely completion of the production process.[8]

SO ORDERED.

RICARDO M. URBINA
United States District Judge

---

[7] The court's action mirrors those taken in other cases in this circuit under similar circumstances. *E.g.*, *Pub. Citizen Health Research Group v. Food & Drug Admin.*, 185 F.3d 898, 900 (D.C. Cir. 1999) (noting that a drug manufacturer intervened to protect allegedly confidential information from disclosure under FOIA); *Pub. Citizen Health Research Group v. Food & Drug Admin.*, 2000 U.S. Dist. LEXIS 4108, at *2 (D.D.C. Jan. 19, 2000) (same).

[8] The court notes that on March 15, 2004, the defendants filed a notice indicating that FDA "anticipates that most of the production of responsive material (i.e., 80-90%) can be completed by April 30, 2004, or within two weeks thereof." Defs.' Notice at 1.